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BACTERIN INTERNATIONAL, INC.

510(k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

November 26, 2007

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Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by a Joseph Azary (Regulatory/Quality Consultant) on behalf of Bacterin International Inc.

Joseph Azary can be contacted by telephone at (203) 944-9320 or fax at (203) 944-9317. Mailing address; 543 Long Hill Avenue, Shelton, CT 06484.

Bacterin International, Inc. is located at 600 Cruiser Lane, Belgrade, MT 59714. Bacterin International, Inc. is registered with FDA under Establishment Registration #3005168462.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade name: *Elutia*™ Coated Closed Surgical Wound Drain

Common/Classification Name: Drainage Catheter, Coated Drainage Catheter

Classification: Classification of this device falls under the responsibility of the Division of General and Plastic Surgery. Class II, Product Code: OEI, 21 CFR 878.4780.

Predicate Device [21 CFR 807.92(a)(3)]

The following predicate devices have been identified:

Wound Drain Comparison

- Johnson & Johnson/Ethicon J-VAC Surgical Wound Drain – K953655

The subject device is similar to the J&J J-VAC Surgical Wound Drain with regard to length, diameter, radiopacity, dot indicator, adaptor, cross section, intended use, sterility, packaging, and flow rate.

The main difference is that the *Elutia*™ Surgical Wound Drain has a hydrogel coating containing silver sulfadiazine.

Silver Coating

- Arrow Blue Central Venous Catheter (Silver Coated) – K900263
- Bard Dialysis Catheter with BioBloc Coating – K053589
- Sil-Med Flat Suction Drain/Kit with Spi-Argent II – K961295

The subject device is coated with silver sulfadiazine. The predicate devices are coated with silver sulfadiazine or ionic silver. The subject device is a wound drain with different dimensions and shapes compared to the Arrow and Bard catheter devices.

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Description of the Device [21 CFR 807.92(a)(4)]

The ***Elutia*** **™ Coated Closed Surgical Wound Drain** is a radiopaque, single-use silicone wound drain with extension tubing for use with available drain reservoirs that include an anti-reflux valve.

The drain is channeled for its entire length. It is available in round or flat configurations and in multiple sizes. A low profile connector joins the drain to clear silicone extension tubing. The drain is packaged sterile in a double pouch and is non-pyrogenic.

The hydrogel coating containing silver sulfadiazine has been shown to reduce bacterial contamination on the surface of the wound drain by greater than 99.99% over a 7 day period as tested under USP <51> conditions against the following microorganisms: *S. aureus, P. aeruginosa, E. coli,* and *C. albicans.* The clinical significance of this finding is unknown.

The subject device is composed of materials that have been successfully used in medical devices including the predicate devices. The subject device is composed of medical grade silicone (indwelling catheter, connector, and external tubing). The device is coated with silver sulfadiazine.

USP grade silver sulfadiazine is used.

The active drug substance is chemically synthesized and does not contain any animal or cell cultures derived from products or additives such as albumin or serum.

The materials used in the subject device have been subjected to and passed biocompatibility testing. Additionally, the materials have been successfully used in other medical devices including the predicate devices.

The subject devices are sterile single-use devices. Sterilization validation was performed.

Intended Use [21 CFR 807.92(a)(5)]

The subject device is intended for the evacuation of biological fluids from wounds or body cavities. Closed wound drainage systems have been used by various specialties including: orthopedic, general, reconstructive, neurological, gynecological, head and neck, thoracic/cardiovascular, and plastic surgery.

Technological Characteristics [21 CFR 807.92(a)(6)]

The subject device is substantially equivalent to the predicate device.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed a variety of biocompatibility, pyrogen, and physiochemical testing per ISO 10993 and USP <29>.

The device and packaging have also been subjected to and passed other testing including Bubble Emission Leak Packaging Tests (per ASTM 2096-04, ISO 11607), Package Burst Testing (per ASTM F1140-00, ISO 11607), and Accelerated Aging Studies.

Conclusion [21 CFR 807.92(b)(3)]

The differences between the subject device and predicate device are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2007

Bacterin International, Inc.
% Azary Technologies, LLC
Mr. Joseph M. Azary
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K063245
Trade/Device Name: Elutia™ Coated Closed Surgical Wound Drain
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: OEI
Dated: October 23, 2007
Received: October 26, 2007

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for Use

510(k) Number:
K063245

Device Name:
Elutia™ Coated Closed Surgical Wound Drain

Indication for Use:
The subject device is intended for the evacuation of biological fluids from wounds or body cavities.

Closed wound drainage systems have been used by various surgical specialties, including: orthopedic, general, reconstructive, neurological, gynecological, head and neck, thoracic / cardiovascular, and plastic surgery.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

____
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)________________

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063245

NOTE DGRND / ODE APP FROM JURISD. PER OVER REVIEW